

Preoperative renal dysfunction does not affect outcomes of left ventricular assist device implantation

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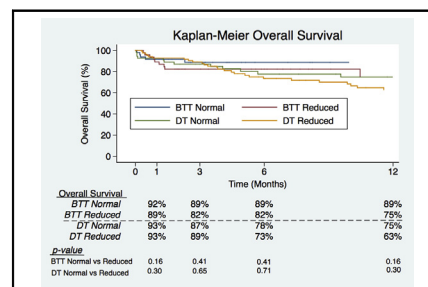
ABSTRACT

Objective: Selection criteria for durable left ventricular assist device (LVAD) implantation remain unclear. One such criterion is renal function. In this study we evaluated outcomes of LVAD implantation in patients with preoperative renal dysfunction.

Methods: Patients with implanted LVADs as destination therapy (DT) or bridge to transplantation (BTT) at a single institution between 2006 and 2015 were included. Primary stratification was according to pre-implantation glomerular filtration rate (GFR): >60 mL/min versus <60 mL/min or dialysis dependence. The primary outcome was post-LVAD implantation overall survival.

Results: Two hundred thirty-eight patients underwent LVAD implantation during the study period as DT (60%; n = 142) or BTT (40%; n = 96). Reduced GFR was present in 56% (n = 132), with 8% (n = 18) being dialysis-dependent. Normal versus reduced GFR cohorts were well matched except for a higher incidence of coronary artery disease in the patients with reduced GFR (61% vs 48%; $P = .04$). Mean follow-up was 13.5 ± 17.0 months. Unadjusted and risk-adjusted survival at 1, 3, 6, and 12 months after LVAD implantation were similar between the cohorts for DT and BTT. Rates of transplantation were comparable in BTT patients (61% normal vs 53% reduced GFR; $P = .43$). Recovery of renal function to a GFR >60 mL/min occurred in 43% (n = 17) and 57% (n = 42) of patients with reduced GFR in the BTT and DT cohorts, respectively, by 1 year post implantation.

Conclusions: Well selected patients with preexisting renal dysfunction can undergo LVAD implantation with acceptable outcomes. Approximately half of LVAD recipients with preimplantation renal dysfunction will recover normal renal function within the first postoperative year. Renal dysfunction alone should not serve as an absolute contraindication to LVAD therapy. (J Thorac Cardiovasc Surg 2018;■:1-9)



One-year survival after LVAD in DT and BTT patients with preimplantation renal dysfunction.

Central Message

Left ventricular assist devices can be implanted in patients with renal dysfunction with acceptable outcomes.

Perspective

Left ventricular assist devices will be implanted in a growing number of patients as the prevalence of end-stage heart failure increases with the aging population. Refining algorithms for patient selection particularly with higher risk cohorts such as those with renal dysfunction will be important to making this effective therapy available to more patients.

See Editorial Commentary page XXX.

Surgical options for end-stage heart failure continue to evolve. Heart transplantation offers the potential for long-term survival, with 20-year survival now a real possibility,

however, its availability is limited by donor shortages. Left ventricular assist devices (LVADs) can be implanted as destination therapy (DT) or as a bridge to transplantation (BTT). The use of LVADs in heart failure, acute and chronic, has increased and will likely continue to increase with the aging population, increases in prevalence of heart failure, improving technology, and better patient outcomes.^{1,2} In cases of DT, 2-year survival of 80% can be achieved in select patients raising the question of when

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Abbreviations and Acronyms

BTT	= bridge to transplantation
CI	= confidence interval
DT	= destination therapy
ECMO	= extracorporeal membrane oxygenation
HR	= hazard ratio
INTERMACS	= Interagency Registry for Mechanically Assisted Circulatory Support
LVAD	= left ventricular assist device
RVAD	= right ventricular assist device

long-term LVAD therapy should be pursued instead of heart transplantation, particularly in patients in whom the latter might not be a reality without a prolonged wait-list time.³

Although outcomes of LVAD therapy continue to improve, there are several barriers to its widespread application. Some areas are universally agreed upon. For instance, LVAD as DT is typically not an option in patients with fixed elevated pulmonary vascular resistance, those with a contraindication to anticoagulation, or in patients with severe right ventricular dysfunction preoperatively. Other areas, particularly as they relate to patient selection, remain controversial. One such area is preoperative renal function. Some groups argue that diminished renal function is a strong predictor of adverse outcomes after LVAD implantation and should be viewed as a contraindication to this therapy.⁴ Others argue that LVAD implantation improves renal function and can be performed with reasonable outcomes in this patient subset, and therefore, that preoperative renal dysfunction should not be an exclusion criteria for LVADs.⁵ In this study, we review our experience with LVAD implantation for DT and BTT in patients with preoperative renal dysfunction.

METHODS**Study Population**

The study population included all LVAD implantations as DT or BTT at a single institution between January 1, 2006 and December 31, 2015. All LVADs in this analysis were continuous flow LVADs with most (79%; n = 187) being HeartMate II (Thoratec Corporation, Pleasanton, Calif). Pediatric patients (younger than 18 years) were excluded. Patients were stratified according to DT versus BTT and preimplantation glomerular filtration rate (GFR): >60 mL/min (normal) versus <60 mL/min or dialysis dependence (reduced GFR). GFR was calculated using the Cockcroft–Gault formula. The institutional review board granted this study exempt status.

Baseline Characteristics

Baseline characteristics were compared between the normal and reduced GFR groups for DT and BTT. Preoperative variables included age, sex, race, weight, height, body mass index, ejection fraction, hemodynamics (heart rate, systolic and diastolic blood pressure, mean arterial pressure, central venous pressure, pulmonary artery pressures, cardiac index,

systemic venous oxygen saturation, wedge pressure, pulmonary vascular resistance, right ventricular stroke work index), comorbidities (coronary artery disease, pulmonary hypertension, chronic obstructive pulmonary disease, diabetes mellitus, smoking, hypertension, hypercholesterolemia, atrial fibrillation, carotid stenosis, cerebrovascular disease, gastrointestinal bleed, thromboembolism, previous myocardial infarction), and laboratory parameters (white blood cell count, hemoglobin, platelet count, blood urea nitrogen, creatinine, sodium, potassium, chloride, carbon dioxide, alanine transaminase, aspartate transaminase, total bilirubin, bicarbonate, lactate, albumin, pre-albumin, international normalized ratio, partial thromboplastin time, lactate dehydrogenase, hemoglobin A1c). Other variables included etiology of heart failure, previous open-heart surgery, milrinone or other inotropic dependence, mechanical ventilation, bridge with extracorporeal membrane oxygenation (ECMO), Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) category, need for intraoperative right ventricular assist device (RVAD), and concomitant procedures such as coronary artery bypass grafting or valve repair or replacement.

Outcomes

The primary outcome was post-LVAD implantation overall survival. Secondary outcomes included major postoperative complications such as re-exploration for bleeding, stroke, reintubation, sepsis, pneumonia, gastrointestinal bleed, acute renal failure requiring dialysis, and arrhythmias. Other secondary outcomes were rates of transplantation in the BTT group and recovery of renal function to a GFR >60 mL/min in the patients with reduced pre-LVAD implantation GFR. GFR was measured at baseline and at 3, 6, and 12 months post-LVAD implantation.

Data Analysis

Kaplan–Meier analyses were conducted to compare the overall post-LVAD implantation survival between the normal and reduced GFR cohorts after stratification on the basis of DT versus BTT. Survival curves were compared using the log rank test. Multivariable Cox regression analyses incorporating univariate predictors (inclusion criteria of 2-tailed $P < .05$) were conducted to evaluate the risk-adjusted effect of reduced GFR on post-LVAD implantation mortality. GFR was modeled as a continuous and a categorical variable in these Cox analyses. Lowess smoothing plots were also constructed to visually depict thresholds of GFR below which the most significant improvements in post-LVAD implantation GFR would be obtained. All continuous data are presented as mean \pm SD and all categorical data as number (percentage). Continuous data were compared with χ^2 and categorical data with Student t test. All statistical analyses were performed with version 11 STATA software (StataCorp LP, College Station, Tex).

RESULTS**Baseline Characteristics**

A total of 273 patients underwent LVAD implantation at our institution during the study period, including 238 who underwent implantation as DT (60%; n = 142) or BTT (40%; n = 96). In the DT cohort, the patients with normal and reduced GFR were well matched with the exception of the reduced GFR patients being older, having more atrial fibrillation, having a lower preoperative hemoglobin level, higher preoperative blood urea nitrogen level, more concomitant tricuspid valve procedures, and using more frequent use of aortic cross-clamp (Table 1). Most LVADs in the DT cohort were implanted for ischemic cardiomyopathy, with most patients being INTERMACS 2 or 3.

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